



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/787,061

02/24/2004

Christian Miculka

612,406-040

9521

34263 7590 12/01/2005

O'MELVENY & MYERS LLP
610 NEWPORT CENTER DRIVE
17TH FLOOR
NEWPORT BEACH, CA 92660

EXAMINER

CRANE, LAWRENCE E

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/787,061

Applicant(s)

MICULKA ET AL.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/24 & 8/27/2004 (preliminary amendments).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

No claims have been cancelled, no claims have been amended, the disclosure has been amended at page 1, and new claims **2-12** have been added as per the preliminary amendments filed February 24, 2004 and August 27, 2004. No Information Disclosure Statements (IDSs) have been filed as of the date of the instant Office action.

Claims **1-12** remain in the case.

The disclosure is objected to because of the following informalities: At pages 1, 3 and 5, structures presented to represent purine and pyrimidine nucleoside analogues are incomplete for failure to provide the double bonds required for proper ring unsaturation. The same problem also occurs in the Abstract. Applicant is referred to the solution incorporated into the parent application's specification and claims.

Appropriate correction is required.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-4** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **10** of U. S. Patent No. **6,696,555 B1** (PTO-892 ref. **K**). Although the conflicting claims are not identical, they are not patentably distinct from

each other because the compounds defined in the conflicting claims are directed to substantially overlapping subject matter.

Claims 1-4 and 9-12 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed exemplifications.

The definitions of both the base oligomeric compounds and compounds including the substituents defined in claim 1-4 and 9-12 are directed to a vast number of radicals derived from other chemical compounds which have not been described in the instant disclosure in a manner permitting the ordinary practitioner to have the guidance necessary to make any of the compounds encompassed. Examiner finds no procedures disclosing the synthesis of oligomeric compounds for the types claimed have been provided in the "Examples" section. Therefore, there is also no disclosure of compounds having a structure with the substituents of the types provided for by the noted claim. Therefore, while examiner agrees that it is possible to chemically attach the instant molecules to a DNA or an RNA, there is insufficient guidance provide by the instant disclosure to support the claimed extension to the other generic members of the Markush group or to "any other biomolecule."

Claims 1-4 and 9-12 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims extends to the conjugation of the instant claimed base molecules to "peptides, proteins, antibodies, functional antibody fragments and any other biomolecule."

B. The nature of the invention is directed to compounds comprising pentopyranosyl oligonucleotides derivatized either at a terminal phosphate substituent or at a nucleotide base moiety.

C. The state of the prior art: the prior art does not appear to disclose any of the claimed compounds.

D. The level of one or ordinary skill cannot be determined because neither the prior art nor the instant disclosure provides the guidance necessary for the ordinary practitioner to practice the instant claimed invention.

E. The level of predictability in the art cannot be determined because the synthesis of the instant claimed compounds are not known and have not been disclosed in the prior art, and have not been described in the instant disclosure.

F. The amount of direction provided by the inventor is limited to unsubstantiated speculations in the disclosure.

G. The existence of working examples: such examples have not been found in the prior art and do not presently exist in the instant case file, either as part of the disclosure or within a supplemental declaration filed under 37 C.F.R. §1.132.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive in view of the complete absence of working examples.

Claims 1-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 at the left end of the structure at line 2, the "vertical wavy line" has not been defined thereby rendering the instant claim incompletely defined. In addition the plural term "nucleotides" found in claims 2, 3 and 4 lacks proper antecedent basis in claim 1 because claim 1 only provides a single nucleotide unit in the structure found at line 2. See also claims 5 and 6-8 wherein the same problem *in re* the term

“nucleotides” appears to be present if only a single pentopyranosyl nucleotide unit is present in the formula provided at line 2.

In claim 1 at lines 3-4, the term “selected from the group consisting of” is followed by a list of compounds, not substituents. Examiner suggests that the noted term should be amended to read -- selected from the group consisting of substituent radicals derived from --. See also claim 9 wherein the same criticism applies.

In claims 1 and 9 the term “any other biomolecule” is indefinite for failure to adequately define and specify the metes and bounds of the subject matter intended to be encompassed thereby.

In claim 1 at lines 3-4, there is a conflict between the lack of the indefinite article in front of each of the first six the Markush group members and the presence of a single variable substituent “A” in the structure at line 2. Examiner suggests that the first 6 Markush group members should be amended to include the indefinite article; e.g. -- a DNA --. See also claim 9 wherein the same criticism applies.

In claim 5 at line 2, the pair of square brackets in the structure is not accompanied by a subscript number, thereby implying that the claimed conjugate is either limited to two nucleotide units or is of unlimited length. Applicant is respectfully requested to clarify the intended meaning or to take other appropriate action. See also claim 9 wherein the same criticism applies.

Claims 5-12 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. §112.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

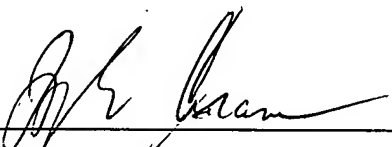
Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number for sending official FAXes to the USPTO is now **571-273-8300**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday. Unofficial FAXes may be sent to the examiner directly at 571-273-0651.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **703-308-1235**.

LECrane:lec
11/28/2005



L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600